UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

PATRICIA SILVA Plaintiff, v. ZIMMER, INC.; ZIMMER HOLDINGS, INC.; & ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS, INC. Defendants.	Civil Action No. _____ COMPLAINT & DEMAND FOR JURY TRIAL

Plaintiff Patricia Silva (hereafter "Plaintiff") by and through her attorneys of record, Lewis Saul & Associates, P.C., hereby files this Complaint & Demand for Jury Trial against Defendants Zimmer, Inc.; Zimmer Holdings, Inc.; and Zimmer Orthopaedic Surgical Products, Inc. (hereafter collectively as "Defendants" or "Zimmer") and alleges as follows:

NATURE OF CASE

1. This products liability lawsuit arises from the failure of a defective Zimmer NexGen® Flex Knee system, a prosthetic knee implant manufactured and sold by Defendants.

2. At all times relevant, Defendants designed, developed, manufactured, promoted, marketed, distributed and sold Zimmer NexGen® Flex Knee system, during which time Defendants repeatedly concealed aberrantly high failure rates with the devices all the while generating substantial revenue from sales of the devices in the United States and throughout the world.

3. The Zimmer NexGen® Flex Knee system includes a number of different models and component parts including the Legacy® Posterior Stabilized-Flex Femoral Components (LPS-Flex), the NexGen® Complete Knee Solution Cruciate Retaining-Flex Femoral Components (CR-Flex), the NexGen® Complete Knee Solution *Gender Solutions*™ Female LPS-Flex (GSF LPS-Flex), the NexGen® Complete Knee Solution CR-Flex *Gender Solutions*™ Female CR-Flex (GSF CR-Flex); and all NexGen® MIS Total Knee Procedure Stemmed Tibial Components (hereafter

collectively the "Zimmer Devices" or "Zimmer NexGen® Flex Knee system" or Zimmer NexGen® Flex Knee family").

4. Data and information that only recently became commonly known and publicly available demonstrate that the Zimmer NexGen® Flex Knee system has extraordinarily high rates of loosening and failure, which caused Plaintiff and other patients like him to develop complications necessitating removal of the devices in "revision" surgeries. A revision surgery is a painful procedure during which some or all of the Zimmer NexGen® Flex Knee system components are explanted from a patient's body and replaced with new components.

5. Plaintiff alleges that problems and defects with the Zimmer NexGen® Flex Knee system, and Defendants' other acts and omissions, some of which are presently unknown to Plaintiff, were the cause of the failure of Plaintiff's Zimmer NexGen® Flex Knee system.

6. Before the date of Plaintiff's initial implantation surgery, Defendants knew, and had reason to know, that the Zimmer NexGen® Flex Knee system was "too challenging" from the perspective of the implanting orthopedic surgeon, that it was defective and presented abnormally high risks of early failure, and that it caused other complications following implantation.

7. Despite both actual and constructive notice of such problems and defects, Defendants continue to this day to market, sell, promote and defend the Zimmer NexGen® Flex Knee system.

8. Defendants failed to warn the medical community and patients, including Plaintiff, of the unnecessary and unacceptable risks posed by utilization of Zimmer NexGen® Flex Knee system orthopedic devices, when there were other available knee implant systems that were safer and would have served the same purpose. Instead, Defendants unlawfully concealed the dangerous problems associated with implantation of the Zimmer NexGen® Flex Knee system.

9. As a result of Defendants' acts and omissions, Plaintiff Timothy Ryder was implanted with a defective Zimmer NexGen® Flex Knee system, resulting in painful and dangerous complications, and has undergone and will undergo future unnecessary and additional

surgery, causing pain and suffering and emotional distress that is ongoing, and causing Plaintiff to suffer other losses and injuries which are permanent in nature.

JURISDICTION & VENUE

10. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiff and all Defendants.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because the Defendants researched, designed, licensed, manufactured, tested, marketed, distributed, and/or sold the Zimmer NexGen® Complete Knee Solution orthopedic device within this judicial district and because Defendants are subject to personal jurisdiction within the State of Maine.

TAG-ALONG ACTION

12. This is a potential tag-along action and, in accordance with 28 U.S.C. § 1407, it should be transferred to the United States District Court for the Northern District of Illinois for inclusion in *In Re: Zimmer NexGen Knee Implant Products Liability Litigation*, MDL No. 2272 (Hon. Rebecca R. Pallmeyer).

THE PARTIES

13. Plaintiff Patricia Silva is an adult resident and citizen of Bath, Maine.

14. Defendant Zimmer, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business located at 1800 West Center Street, Warsaw, Indiana 46581. At all times relevant to this action, Defendant Zimmer, Inc. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold Zimmer NexGen® Complete Knee Solution orthopedic devices in interstate commerce and throughout the State of Maine and generated substantial revenue as a result.

15. Defendant Zimmer Holdings, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business located at 1800 West Center Street, Warsaw,

Indiana 46581. At all times relevant to this action, Defendant Zimmer Holdings, Inc. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold Zimmer NexGen® Complete Knee Solution orthopedic devices in interstate commerce and throughout the State of Maine and generated substantial revenue as a result.

16. Defendant Zimmer Orthopaedic Surgical Products, Inc. is a corporation organized and existing under the laws of Ohio, with its principal place of business located at 200 West Ohio Avenue, Dover, Ohio 44622. At all times relevant to this action, Defendant Zimmer Orthopaedic Surgical Products, Inc. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold Zimmer NexGen® Complete Knee Solution orthopedic devices in interstate commerce and throughout the State of Maine and generated substantial revenue as a result.

MISNOMER/ALTER-EGO

17. In the event any parties are misnamed or not included herein, it is Plaintiff's contention that such a misnomer and/or such parties are/were "alter egos" of parties named herein. Alternatively, Plaintiff contends that such "corporate veils" should be pierced to hold such parties properly included in the interest of justice.

GENERAL FACTUAL ALLEGATIONS

I. Basic Anatomy of the Knee

18. From a lay perspective, the knee is a hinge joint where the ends of the thigh bone and the shin bone move principally in one plane like a hinge. However, the actual function of this anatomy is much more complex, as the bones are not directly attached to each other but are held together by rope-like ligaments. Movement is created by the action of muscles and tendons. The joint hinge bears weight directly on its principal articulating surfaces which are made of specialized cartilage.

19. The knee is composed of three functional bones: the femur (thighbone), tibia (shinbone) and patella (kneecap). The femur is the longest and strongest bone in the body. The distal end (the lower end farthest from the center of the body) forms the upper part of the knee. This distal end has double rounded knob-like projections (the "condyles") with a groove in between. One condyle is on the medial (inside) of the knee, and the other on the lateral (outside) of the knee. These rounded condyles articulate (move) along the top of the tibia while the back of the patella (kneecap) moves along the groove between the condyles.

20. The femur and the tibia meet to form a pivotal hinge joint, permitting flexion (decrease of the joint angle) and extension (increase of the joint angle or straightening) of the leg as well as slight medial and lateral rotation.

21. The knee joint is protected in front by the patella (kneecap). The patella is a mostly flat, oval shaped, sesamoid bone tapered toward the distal end. Sesamoid means the bone is contained within a tendon in this case, the patellar tendon. The posterior or back side, of the patella slides between the condyles of the femur and articulates with the femur.

22. The joint is cushioned by articular cartilage that covers the ends of the tibia and femur as well as the underside of the patella. The articular cartilage is linked to the underlying bone by a complex geometric interlocking system, much like jigsaw puzzle pieces. Bone and cartilage are not connected in any way other than a mechanical connection, and are anatomically separate, with separate systems for growth, nutrition and regeneration.

23. Arthritis develops when the cartilage surface wears away creating increased pressure on the bone and therefore pain. Damage to the surface causes the cartilage to lose its firmness and increase wear. Damage is repaired by fibrous tissue which does not have the same properties as the original tissue. "Arth" means joint. The suffix "osis" means damage. The suffix

"itis" means inflammation. In osteo-arthritis, decreased elasticity and reduction in load bearing capability occurs.

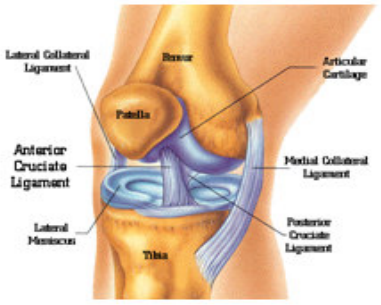
24. Two other parts of the articulating joint are the menisci ("meniscus" singular). The lateral meniscus and medial meniscus are pads of cartilage that further cushion the joint, acting as shock absorbers, spreading the impact of motion across the joint surfaces.

25. Ligaments stabilize the knee. The medial collateral ligament (MCL) and lateral collateral ligament (LCL) are known as the extracapsular ligaments and run on the sides of the knee. Their role is essentially to hold the femur and tibia together and resist side to side motion.

26. The anterior cruciate ligament (ACL) and the posterior cruciate ligament (PCL) are known as intra-articular ligaments and likewise hold the femur and tibia together, and resist forward and backward sliding of the femur over the tibia.

27. The main motions of the knee joint are flexion (bending) and extension (straightening), with limited medial and lateral rotation. The main muscles responsible for extension are the quadriceps, which are also the most important muscle in stabilizing the knee joint. Flexion is produced by group of muscles known as the hamstring muscles.

28. There are two articulations or points where the bones make contact: femur and tibia; and femur and patella.



II. Flexion and Extension of the Knee

29. The principal movements of the knee joint are flexion (which is bending the knee), and extension (which is straightening the knee). Typically, a healthy knee has the potential to bend to about 155 to 160 degrees. One limiting factor on flexion is the girth of the leg, so that the knee may not reach 155 degrees even though it is anatomically able to do so because the soft tissues of the thigh and calf hit each other. The healthy knee can typically extend just beyond 0 degrees.

30. Most normal movements of everyday life such as walking, climbing and descending stairs, getting out of a chair, getting in and out of a car, or stooping generally require only up to 90 degrees of flexion. A modestly active person needs only about 95 degrees of flexion to engage in normal activities of daily living.

31. Infrequently, activities of daily living require up to 120 degrees of flexion, for example, getting up off the floor, or getting out of a seat where the hip is lower than the knee when seated. Some infrequent activities of daily life require flexion beyond 120 degrees. For example, in some instances climbing stairs requires between 75-140 degrees, sitting in a chair and standing up again may require between 90-130 degrees, and squatting (e.g. while gardening) requires between 130-150 degrees.

III. The Total Knee Replacement Procedure

32. Total knee arthroplasty ("TKA"), also called total knee replacement ("TKR"), is a commonly performed medical procedure. The surgery is designed to help relieve pain and improve joint function, generally in people with severe knee degeneration due to arthritis or trauma.

33. Knee replacement is the process of replacing the joint surfaces with artificial materials. The replacement is not nearly as good as the original but it redistributes weight and takes away the tissue causing inflammation and thus reduces pain. Replacement requires a mechanical

connection between the bones and the implant components, but this bonding is never as good as the natural bonding of cartilage to bone.

34. A total knee arthroplasty is a misnomer, in that it is not truly a total knee replacement, but rather the resurfacing of damaged articular cartilage and bone surfaces. The main goals of the procedure are: (1) to relieve pain caused by arthritis, (2) to restore range of motion, or the degrees of knee flexion and extension, and (3) to correct any varus and valgus misalignment.

35. A total knee replacement is usually considered when disease or injury cause substantial damage to the surface of either bone or the underside of the patella.

36. The TKA procedure is done by separating the muscles and ligaments around the knee to expose the inside of the joint. The ends of the femur and tibia are removed or reduced as is often the underside of the patella.

37. In total knee replacement surgery, the surface of the femur is replaced with a contoured metal component designed to fit the curve of the bone. The surface of the tibia is typically replaced with a flat metal component and a smooth plastic component that serves as a replacement for cartilage. The undersurface of the patella may also be replaced with an implant made of plastic, or a combination of metal and plastic.

38. Globally, hundreds of thousands of knee replacement procedures are performed each year, with 500,000 performed in the United States alone.

39. Ordinarily, most total knee replacements are successful up to ten years.

IV. History of Zimmer and the Zimmer NexGen Family of Flex Knees

40. Zimmer was founded in 1927, and purports to be a worldwide leader in the design and manufacture of orthopedic reconstructive, spinal and trauma devices, dental implants, and related orthopedic surgical products.

41. In 1927, Justin Zimmer, a national sales manager for Depuy, an orthopedic splint manufacturer, broke away and started Zimmer Manufacturing Company. Originally a company that manufactured aluminum orthopedic braces, it quickly expanded into the surgical implant business. Today, Zimmer designs, develops, manufactures and markets orthopedic implants as well as fracture products and surgical tools.

42. In 1995, Zimmer introduced its Next Generation (NexGen) Complete Knee Solution system, with various component configurations as well as surgical guides and tools. Designed largely by John Insall, the system received FDA 510(k) clearance, demonstrating that the device was "substantially equivalent" to predicate devices previously approved by the FDA.

43. The NexGen TKR was an integrated system combining a femoral component, a tibial component, a plastic articulating surface and a plastic replacement for the posterior surface of the patella. The surgeon had the option to save or remove the posterior cruciate ligament.

44. With the NexGen CR (Cruciate Retaining) implant, the PCL is preserved. In the LPS (Legacy Posterior Stabilized) version the posterior cruciate ligament is sacrificed.

45. The LPS implant includes a raised surface with an internal post on the tibial component that fits into a special notch on the femoral component. The post and notch work together to perform the function of the PCL: preventing the tibia from moving too far backward.

46. The basic system was very successful with a low revision rate. The system was able to achieve flexion up to between 120 and 130 degrees, depending on the patient.

47. Over time, Zimmer became the largest U.S. manufacturer of knee replacement devices.

48. Knee replacement is Zimmer's largest single line of business, with sales from knees alone exceeding $1.7 billion in 2010, amounting to 42% of company revenue.

49. Despite the success of the NexGen Complete Knee Solution system and other Zimmer products, the knee replacement manufacturing industry remains highly competitive with at least four other major manufacturers.

50. While the standard NexGen CR (Cruciate Retaining) and NexGen LPS (Legacy Posterior Stabilized or cruciate sacrificing) produced excellent results and sales, the push to increase market share or expand the market to younger more active patients caused sellers to design implants that could arguably provide more function or were more attractive to the consumers, whether the consumer was a patient, a hospital, a health system or a surgeon.

51. The first step in that direction was the NexGen LPS Flex Fixed-Bearing Knee was which got FDA 510(k) approval in 1999 and was introduced in 2001. The LPS-Flex was designed to allow for a maximum flexion of 155 degrees.

52. The NexGen CR Flex followed in 2003, also allowed up to 155 degrees of flexion.

53. In 2004, Zimmer launched its Minimally Invasive Solutions (MIS) Quad-Sparing TKR Procedure. Whereas traditional TKR incisions are 8-12 inches, Zimmer's MIS incision is 3-5 inches and avoids cutting a portion of the quadriceps muscles and tendon. The stated goals were less blood loss, less pain, a shorter hospital stay, and shorter rehabilitation. On the negative side, a smaller opening limited the surgeon's view of the operative field, and required some specialized and smaller instruments and components.

54. In 2006, Zimmer launched Gender Solutions, a femoral component designed specifically for women. Differences between traditional and Gender Solutions Female (GSF) implants include a thinner profile, contoured shape, and a difference angle between the pelvis and the knee to more mimic the general anatomic differences between the female and male knee (other than size).

V. Regulatory History of Zimmer NexGen Knees

55. In 1995, Zimmer received approval from the United States Food and Drug Administration ("FDA") for its NexGen Complete Knee Solution Legacy LPS Knee system as well as for its NexGen CR Knee system. These designs would become the predicate devices for the "high-flex" designs that were to be introduced by Zimmer over the next decade and a half.

56. The Zimmer NexGen Complete Knee system and component parts are all interrelated and predicated upon the same design, and may be graphically summarized as follows:

57. The interrelationship of the Zimmer NexGen Knee System: LPS-Flex, CR-Flex, GSF LPS-Flex, GSF CR-Flex and MIS Tibial Components is admitted within Zimmer submissions to the FDA.

58. Zimmer's stated design rationale for the Zimmer NexGen Flex Knee includes the statement that "[b]oth CR-Flex and LPS-Flex knees are designed to safely accommodate flexion of up to 155º. Moreover as postoperative flexion can be somewhat unpredictable, the CR-Flex and LPS-Flex knees have been designed for use *in all patients, including those who do not appear to have the need to achieve higher flexion*." (emphasis added).

59. Zimmer further states that common design issues to both the CR-Flex and LPS-Flex "relate to contact area between the femoral component condyles and the tibial articular surface during deep flexion, stresses on the extensor mechanism during deep flexion, patellar tracking, sizing to facilitate balancing of the flexion and extension gaps, and anterior lift-off of the tibial articular surface."

60. Zimmer also notes that with respect to the CR-Flex and LPS-Flex, "[i]nterchangeability among the components allows the surgeon to switch from the cruciate retaining design to the posterior stabilized design intraoperatively."

A. 510(k) Approval of the LPS-Flex Knee

61. Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification and is also called PMN or 510(k). This allows FDA to determine whether the device is substantial equivalent to a device already approved for marketing.

62. The Legacy Posterior Stabilized Flex Knee (LPS-Flex) was marketed by Zimmer as "intended for patients who have adequate bone stock and whose ligaments provide moderate joint stability or for when the posterior cruciate ligament has been cut or removed."

63. In July 1999, Zimmer received FDA 510(k) approval of its first NexGen Flex knee, the Complete Knee Solution Legacy Posterior Stabilized (LPS); LPS-Flex Fixed Bearing Femoral and Articular Surface Components, commonly known as the LPS-Flex Fixed Bearing Knee.

64. Zimmer's 510(k) Summary of Safety and Effectiveness submitted to the FDA in May 1999 seeking approval for the LPS-Flex Fixed Bearing Knee, states the predicate device was the NexGen Complete Knee Solution Legacy LPS Knee.

65. Zimmer's 510(k) Summary of Safety and Effectiveness further claimed that the LPS-Flex Fixed Bearing Knee was similar to the predicate device in design, materials and performance, and identical to the predicate device sterility, biocompatibility and pyrogenicity noting, "[e]ven though the LPS-Flex increases the maximum active flexion angle to 155 degrees, the design has maintained the conformity necessary to minimize or eliminate any new movement mechanisms that could affect wear."

66. The LPS-Flex Fixed Bearing Knee received approval in July 1999 at which time the FDA determined it was "substantially equivalent" to the predicate device.

B. 510(k) Approval of the CR-Flex Femoral Components

67. Like the LPS-Flex, the Cruciate Retaining Flex Knee (CR-Flex) was marketed by Zimmer as "intended for patients who have good bone stock and whose ligaments provide adequate joint stability."

68. When Zimmer approached the FDA for 510(k) approval for the CR-Flex device, it claimed that the device was substantially similar to a sister device in the self-named "Zimmer Flex-Series."

69. In Zimmer's 510(k) submission for the NexGen CR-Flex Zimmer listed two predicate devices: 1) NexGen LPS-Flex and NexGen CR. Zimmer's own description of the comparison to the predicate devices states "except for modifications to allow flexion to 155 degrees, CR-Flex femoral components are *identical* to the predicate device. The modifications do not change the intended use or the fundamental scientific technology the device is packaged and sterilized using the same materials and processes."

70. In October 2002, Zimmer received FDA 510(k) approval of its NexGen Complete Knee Solution Cruciate-Retaining (CR)-Flex Femoral Components at which time the FDA determined it was "substantially equivalent" to the predicate device.

C. 510(k) Approval of Gender Solutions Female (GSF) LPS-Flex and CR Flex Knees

71. In February 2006, Zimmer submitted one 510(k) application to the FDA for both the LPS-Flex and CR-Flex NexGen Gender Solutions Female "GSF" implants, which are also described as part of the "Zimmer Flex Series." The predicate devices were listed as the NexGen LPS-Flex and the CR-Flex and in its comparison to the predicate devices Zimmer states "Except for modifications to address specific anatomic features typical of a female patient, these

components are *identical* to their respective predicate device. The device is packaged and sterilized using the same materials and processes."

72. Zimmer's February 2006 510(k) Summary of Safety and Effectiveness further noted that the "NexGen Knee GSF Femoral Components included both LPS-Flex GSF and CR-Flex GSF versions and are part of the Zimmer-Flex series of semi-constrained, nonlinked, condylar knee prostheses that are designed to have a maximum active flexion of 155 degrees."

73. The NexGen Knee Gender Solutions Female (GSF) Femoral Components received approval in April 2006 at which time the FDA determined it was "substantially equivalent" to the predicate device.

D. 510(k) Approval of the MIS Tibial Components

74. The Zimmer NexGen Knee also uses a stemmed tibial component that is designed to be assembled within the patient thereby allowing for minimally invasive surgery techniques.

75. In March 2005, Zimmer received 510(k) FDA approval for the NexGen Complete Knee Solution MIS Tibial Components. The MIS Tibial Components are part of the NexGen system of semi constrained, non-linked, condylar knee prostheses.

76. Zimmer's 510(k) Summary of Safety and Effectiveness submitted to the FDA in November 2004 seeking approval for the NexGen Complete Knee Solution MIS Tibial Components noted that the "NexGen Complete Knee Solution MIS Tibial Components are part of the NexGen system of semi constrained, non-linked, condylar knee prostheses." The application relied upon both the LPS-Flex and the CR-Flex as the prior approved devices that share substantial equivalence.

77. The low profile design of this tibial component was developed and manufactured by Zimmer to allow for implantation and assembly in Minimally Invasive Surgical procedures

("MIS"). In a standard knee replacement surgery the incision is roughly eight inches. Conversely, a MIS surgery only requires a four to five inch incision. The theory behind the MIS surgical procedure is that the reduced incision leads to quicker healing and recovery times. Unfortunately, the theory did not play out in practice, and ultimately resulted in a more difficult procedure prone to increased failure rates.

78. Upon information and belief, Defendants were in control of the design, assembly, manufacture, marketing, distribution, packaging, labeling, processing, supplying, promotion, sales, and the issuance of product warnings and related information with respect to the NexGen® Complete Knee Solution system devices.

79. In seeking approval for the sale of the Zimmer NexGen® Flex Knee system, Defendants represented that each of the implants was substantially equivalent to a previously approved or predicate device and therefore could receive premarket approval under Section 510(k) of the FDA.

80. By claiming substantial equivalence, Defendants knew the Zimmer NexGen® Flex Knee system was subject to far less testing and scrutiny.

VI. Zimmer Marketing of NexGen Knees

81. With the introduction of the Insall knee described above and other basic knee designs, the market became crowded with knee prostheses that could reliably eliminate pain and restore the ability to perform most daily functions with a low failure rate.

82. The only ways to increase market share was to either expand the patient base of those who receive implants (for example, younger more active patients) or offer TKR with alleged enhancements such as more function, shorter recovery times or prostheses designed to gender specifications.

83. Referred to in some publications as "premium knees", the new designs were more expensive but at the same time more attractive to many patients and surgeons.

84. Zimmer took the lead in this area with three different enhancements. First, the basic NexGen LPS and CR knees were redesigned so they had the potential to flex a full 155 degrees. Next, the minimally invasive surgery, or MIS (Minimally Invasive Solutions), promised a quicker exit from the hospital and quicker recovery. Finally, the "Gender Solutions" knee, all of which were flex knees, were redesigns of the standard CR and LPS, but shaped slightly different to mimic the typical anatomical differences between a male and female knee.

85. With these alleged improvements, patients were promised that they could recover faster, and engage in more active lifestyles.

86. Women, who were roughly two-thirds of the knee implant market, were told they could get a knee replacement designed just for them.

87. The Zimmer NexGen Flex Knee, including but not limited to the Zimmer LPS-Flex, CR-Flex, LPS-Flex (GSF), CR-Flex (GSF) and/or MIS Tibial Components and any and all other Zimmer high-flexion knee systems and/or components predicated directly or indirectly upon the LPS-Flex Fixed Bearing Knee were aggressively marketed and promoted to the more active population, including Plaintiff herein, promising state-of-art knee replacement providing greater flexion up to 155 degrees, and allowing for minimally invasive knee replacement.

88. Zimmer stated that the Flex Fixed Knee replacement was the first knee specifically designed to safely accommodate flexion of up to 155 degrees.

89. This information is part of a public awareness campaign by Zimmer, known as "Keeping pace with life," designed to educate patients about the Flex Fixed Knee as an option for total knee replacement.

90. The stated campaign goal is to provide patients with information and insight into the leading edge treatment for joint replacements to help them make educated decisions about their course of treatment.

91. In the U.S., Zimmer has aggressively marketed its high-flex versions as specifically designed for younger and more active total knee replacement patients "expecting to maintain an active lifestyle."

92. In marketing materials touting its NexGen flex products, Zimmer explicitly acknowledged the lack of studies surrounding joint motion, yet unabashedly pushed to expand the market in the U.S. to literally create a need for its product.

93. Zimmer admitted that "in recent years, total knee arthroplasty (TKA) has brought about increasingly better, functional results and greater satisfaction to patients. Traditionally, 110 degrees to 115 degrees average passive flexion associated with TKA has been sufficient for Western patients. Western patients whose activities of daily living (ADL) involve chairs and beds may be content with a knee range of motion of 115 degrees."

94. Nevertheless, Zimmer went on to say in trying to expand its market, Asian and Middle East patients may need greater flexion to adjust to the cultural demands of daily life where "normal range of motion…is considered to be between 130 degrees and 155 degrees."

95. Zimmer then attempted to provide justification for expanding the market in the U.S. to provide the type of flexion required by Asian and Middle Eastern cultures: "There have been only a few studies published regarding the normal range of joint motion, and most of these are from the Western Hemisphere. As the reach of our designs becomes more global, we know that there are many other cultural activities and lifestyles that require considerably more squatting and kneeling activities in everyday life."

96. Without any self-restraint, Zimmer went on to create its flex market: "the desire or need for flexion in excess of 115 degrees after TKA is not isolated to Asian and Middle East cultures only. There are Western patients that need the ability to achieve high flexion of the knee because of recreation and/or religious activities. Gardening is still a popular pastime and may require sitting on a low stool or kneeling. People of Roman Catholic faith often pray while kneeling, and the process of getting in and out of a kneeling position can be aided by high flexion capability."

97. Zimmer's approach to the aggressive – yet inadequately supported for safety or efficacy – campaign for the MIS Tibial device and procedure was no different.

98. A principle component of Zimmer's marketing of the Zimmer Devices was the allure of the MIS surgical procedure, so much so that Zimmer went to the extensive effort to trademark the term "MIS" or "Minimally Invasive Solutions."

99. Zimmer's MIS Tibial components were marketed as "specifically designed to address the challenges and demands of minimally invasive TKA." To achieve these goals, the design incorporated broad proximal fins that engage the tibia, while its low profile makes it easier to insert.

100. Zimmer's promotional materials were specifically designed to induce physicians and patients that the use of the MIS Tibial components involved "MIS procedures are less invasive with smaller incisions, reduced blood loss, less pain and shorter hospital stays."

101. By 2010, Zimmer was forced to admit that its marketing was false and that MIS procedures would not result in reduced risk.

102. In April 2010, Zimmer sent an "Urgent Field Safety Notice"/"Urgent Device Correction" letter to all customers using the Zimmer NexGen MIS Tibial. With the urgent notice, gone were the claims of "less invasive" and "shorter hospital stays." Zimmer admitted that "MIS procedures are inherently challenging and can involve reduced visibility, which may lead to difficulty with achieving proper implant alignment and cement fixation."

103. On September 13, 2010, the FDA classified Zimmer's efforts relating to the NexGen MIS Tibial components as a Class II Recall. About 68,384 MIS Tibial components contained defective surgical instructions and warnings.

104. Despite Zimmer's marketing statements, its NexGen Knees identified herein provided little or no benefit as compared to traditional knee replacements, and began to fail in patients at alarming rates.

VII. Lack of Efficacy and Failure of Zimmer NexGen Knees

105. There are several reasons for the failure of knee implants. The primary reason for failure implicated in this litigation is "mechanical loosening." Mechanical "loosening" means that the attachment between the artificial knee and the existing bone has become loose.

106. Loosening can occur with any component of the artificial knee, including the femoral, tibial or patellar components.

107. Loosening of an artificial knee can be visualized and diagnosed using radiographic imaging. Images of a loose knee joint are one or more radiolucent lines around the contours of the artificial knee joint.

108. A loose artificial knee causes pain and wearing away of the bone. A loose artificial knee can involve a severe physical burden for the patient and severely restrict the patient's daily activities.

109. Once the individual loses function of the knee or the pain becomes unbearable, another operation can be required to revise the knee replacement. A loose, painful artificial knee can usually, but not always, be replaced.

110. The purpose of knee revision surgery is to remove a failed knee implant and replace it with a new one.

111. In an operation revising a total knee failure due to loosening, the most significant problem is often the reconstruction of the severe bone loss caused by the failed total knee prosthesis. The bone loss makes it difficult to restore the stability in the revised total knee.

112. The success rate of a revision operation is lower than that of the initial total knee replacement and the risks and complications are higher. The range of motion in the knee after revision surgery may decrease and the ability to walk may also be diminished. The rate of an artificial knee replacement loosening is higher after revision surgery than in primary knee replacement surgery.

113. There is a significant body of published literature as well as attention from the media and the United States Congress concerning greater than expected loosening and failure rates requiring revision surgery for the Zimmer NexGen® Flex Knee system.

A. An Overview of the Problems Associated with NexGen Flex Knees

114. Throughout the past several years, there has been an increasing drum beat of evidence establishing that the so-called "High-Flex" knees: a) fail to provide additional or

meaningful flexion beyond 120º; and b) fail at an artificially high rate when compared to their non-flex equivalents.

115. Starting in 2005, a study published in the Journal of Bone and Joint Surgery by Young-Hoo Kim entitled, Range of Motion of Standard and High-Flexion Posterior Stabilized Total Knee Prostheses, established no statistical significance between the degrees of flexion in a group with a traditional LPS prosthesis versus a group with the LPS-Flex. Specifically, the authors reported that after two years, the mean range of motion/flexion in the LPS group versus the LPS-Flex group was a mere three degrees.

116. The *Kim* study was followed by a report in 2007 in The Journal of Bone and Joint Surgery (British Edition), published a peer reviewed study by professors at the Seoul National University College of Medicine entitled, High Incidence of Loosening of the Femoral Component in the Legacy Posterior Stabilized-Flex Total Knee Replacement. This study showed that 38% of the implanted LPS High Flex knees were loose shortly after two years post-implantation. From the group of patients with loose knees, over half (56%) had their knee revised due to pain.

117. In 2010, a new study by SD Cho published in Knee Surgery, Sports Traumatology, Arthroscopy questioned the efficacy of high flex knees, specifically the LPS-Flex. In the article, entitled, Three to six year follow-up results after high-flexion total knee arthroplasty: Can we allow passive deep knee bending?, the authors concluded that the LPS-Flex knees were associated with a relatively high incidence of early loosening of the femoral components. Dr. Cho, the principle author of the study, stated that squatting or kneeling may not even be permitted after implantation of the LPS-Flex given these adverse effects.

118. In all, several peer reviewed studies have looked at the benefits of Zimmer's high-flex knees compared to standard knees and they repeatedly find that patients with the high-flex knees do not have better range of motion (ROM) than patients with the standard knees.

119. In fact, a recent study published in 2010 provided a meta-analysis of these studies, the majority of which involved NexGen knees. It reviewed and analyzed data from eleven studies comparing a total of 561 high-flex knees with 563 standard knee implants. Seven of the trials

looked at Posterior Stabilized designs and four trials compared the Cruciate Retaining design implants. The analysis revealed that patients in each group, the high-flex and the standard, achieved an average post-operative ROM of 110 degrees. The analysis also revealed no statistical differences in knee ROM, weight-bearing flexion, knee scores and complications among the two groups.

120. Studies surrounding the NexGen Gender Solutions flex line have found similar lack of efficacy relating to the altered design which is claimed to provide a better fit for a female knee.

121. There have been several comparison studies looking at the outcomes of the NexGen Gender Solutions knee implants compared to their non-gender flex counter parts. A 2010 study involving 85 women who received the LPS-Flex in one knee and the Gender Solutions LPS-Flex in the other knee found no significant clinical benefits between the two groups. The mean range of motion was 125 degrees for the LPS-Flex and 126 for the gender specific LPS-Flex.

122. Another comparison study involving 138 women who received the CR-Flex in one knee and the Gender Solutions CR-Flex in the other, yielded the same results. The range of motion was 123 and 127 respectively for the two groups.

123. The scrutiny of Zimmer's failed high flex knees has not been limited to the peer reviewed medical literature.

124. On June 19, 2010 the *New York Times* unveiled an expose detailing an unacceptably high rate of failure rate for CR-Flex devices.

125. The *Times* article reported on the findings of a former Zimmer consultant, Dr. Richard A. Berger.

126. Specifically, Dr. Berger raised concerns with Defendants regarding unacceptable failure rates of the CR-Flex. Berger, an orthopedic surgeon at Rush University Medical Center in Chicago, performed thousands of knee replacements almost exclusively using Zimmer products.

127. While a consultant for Zimmer, the company publicly praised Dr. Berger for his outstanding technique.

128. Ultimately, Dr. Berger along with a colleague at Rush University Medical Center, Dr. Craig Della Valle, performed a study which they presented at the American Association of Orthopaedic Surgeons in March 2010.

129. Specifically, Drs. Berger and Della Valle found that nearly ten percent of the devices they implanted failed and about half of the 100 patients studied showed signs of aseptic loosening. Rather than acknowledging the results, Zimmer instead responded to the findings by blaming Dr. Berger's surgical technique and disclaiming a defect in their product.

130. On July 29, 2010, US Senator Charles Grassley, disturbed by the *New York Times* story, sent a letter to Zimmer's President and Chief Executive Officer expressing concerns over the safety of the Zimmer NexGen Flex Knees in question. Senator Grassley directed Zimmer to address numerous safety concerns, including the processes Zimmer had in place to respond to concerns raised by its consultants regarding the safety of one of its products, whether the concerns led to safety modifications, and whether Zimmer voluntarily collected data on the performance of its knee devices and other implantable devices.

131. According to Senator Grassley's letter a response was requested by August 12, 2010. To date, Zimmer's response, if any, has not been made public. But the reports serve as a major signal that thousands of individuals may have claims related to the failure of loosening of the Zimmer NexGen Knees.

132. Since 2003, Zimmer has manufactured and sold approximately 150,000 Zimmer NexGen High-Flex Knee implants.

133. From the time that Defendants first began selling the Zimmer NexGen High-Flex Knee the product labeling and product information for the Zimmer NexGen Flex Knee failed to contain adequate information, instructions, and warnings concerning implantation of the product and the increased risks that the Zimmer NexGen High-Flex Knee can loosen in patients.

134. Despite its knowledge of the serious injuries associated with use of the Zimmer NexGen High-Flex Knee, Defendants engaged in a marketing and advertising program which

falsely and deceptively sought to create the image and impression that the use of the Zimmer NexGen Flex Knee was safe.

135. Upon information and belief, Defendants downplayed and understated the health hazards and risks associated with the use of the Zimmer NexGen High-Flex Knee through promotional literature as well as sales visits to orthopedic surgeons, deceived doctors and potential users of the Zimmer NexGen Flex Knee by relaying positive information, while concealing the nature and extent of known adverse and serious health effects.

B. An Overview of the Problems Associated with MIS Tibial Components

136. The MIS Tibial components were marketed as the first component to be designed for the MIS surgical procedures. It is generally used with NexGen CR/CR-Flex and NexGen LPS/LPS-Flex articular surfaces, as well as with the Gender Solutions Female models to facilitate insertion through a smaller soft tissue window in which muscle and tendon cutting is minimized.

137. In March 2010, Dr. Steven Weeden, of the Texas Hip and Knee Center, presented a study at a national meeting of the American Association of Orthopedic Surgeons reporting a higher than expected rate of early loosening in cemented primary total knee replacements when a MIS Tibial component was used without an additional modular stem. In the MIS Tibial components placed without an additional modular stem the failure rate was 24% versus 4.2% with a stem.

138. Notwithstanding the claims made by Zimmer regarding the MIS Tibial component, in or around April 2010, Defendants sent an "Urgent Field Safety Notice"/"Urgent Device Correction" letter to all customers using the MIS Tibial.

139. In that letter, Defendants acknowledged, in a stunning reversal of prior promotion and marketing of the MIS Tibial Component, that the prior procedures were wrong and potentially dangerous.

140. Specifically, whereas before Defendants marketed MIS procedures, including the MIS Tibial as "less invasive with smaller incisions, reduced blood loss, less pain and shorter

hospital stays," Defendants admitted that "*MIS procedures are inherently challenging and can involve reduced visibility*, which may lead to difficulty with achieving proper implant alignment and cement fixation" (emphasis added).

141. Defendants went on to alert physicians that "Required Actions" included "destroy or disregard all previous versions of the surgical technique [MIS]."

142. Finally, Defendants advised customers of a change in labeling and recommended usage of the MIS Tibial Component in several important ways:

a. To achieve adequate visualization and access if an MIS approach is used,

b. To use a drop down stem extension with the NexGen MIS Tibial Component,

c. To fully cement and pressurize the anterior and posterior surfaces of the tibial component, and

d. To carefully use bone cement application per the manufacturer's instructions.

143. As of September 12, 2010, Zimmer had received numerous complaints of loosening of the implanted device requiring revision surgery. There had been 114 MDRs (Medical Device Reports) filed. All reported that the device loosened and the patient required additional surgery to replace the device.

144. On September 13, 2010, the FDA classified the Defendants efforts relating to the MIS Tibial components as a Class II Recall.

145. From the time that Defendants first began selling the Zimmer NexGen MIS Tibia, the product labeling and product information for the Zimmer NexGen MIS Tibia failed to contain adequate information, instructions, and warnings concerning implantation of the product and the increased risks that the Zimmer NexGen MIS Tibia can loosen in patients.

146. Despite its knowledge of the serious injuries associated with use of the Zimmer NexGen MIS Tibia, Defendants engaged in a marketing and advertising program which falsely

and deceptively sought to create the image and impression that the use of the Zimmer NexGen MIS Tibia was safe.

147. Upon information and belief, Defendants downplayed and understated the health hazards and risks associated with the use of the Zimmer NexGen MIS Tibia through promotional literature as well as sales visits to orthopedic surgeons, deceived doctors and potential users of the Zimmer NexGen MIS Tibia by relaying positive information, while concealing the nature and extent of known adverse and serious health effects.

SPECIFIC FACTUAL ALLEGATIONS

148. On January 23, 2009, Plaintiff Silva underwent a right total knee arthroplasty using a Zimmer NexGen® Flex Knee system.

149. Thereafter, Plaintiff began to experience pain and discomfort in her right knee.

150. In February 2011, Plaintiff Silva underwent a right knee revision procedure due to loosening of her Zimmer NexGen® Flex Knee system.

151. As a direct, proximate and legal consequence of the Zimmer NexGen® Flex Knee system, and its defects and failures as described herein, Plaintiff has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, severe pain and discomfort; poor balance; difficulty walking; popping, clicking and grinding noises; bone erosion; implant loosening, impingement and/or detachment; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of Zimmer NexGen® Flex Knee system, Plaintiff Silva has sustained and will sustain future damages, including but not limited to, additional revision surgeries; cost of medical care, rehabilitation, home health care, lost wages, loss of earning capacity, mental and emotional distress, and pain and suffering.

FIRST CAUSE OF ACTION
STRICT LIABILITY – MANUFACTURING DEFECT

152. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

153. Prior to, on, and after the dates of Plaintiff's initial knee surgery, and at all relevant times, Defendants designed, distributed, manufactured, sold, and marketed the Zimmer NexGen® Flex Knee system for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States.

154. The Zimmer NexGen® Flex Knee system was "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the Zimmer NexGen® Flex Knee system was in a condition not suitable for its proper and intended use.

155. At all times herein mentioned, the Defendants designed, manufactured, distributed, marketed and sold the above-described Zimmer NexGen® Flex Knee system, which was implanted in Plaintiff, such that it was dangerous, unsafe, and defective in manufacture. The defects included, but were not limited to, the fact that the Zimmer NexGen® Flex Knee system had a tendency to detach, disconnect, and/or loosen, cause pain, inhibit walking, and require revision surgery.

156. Upon information and belief, the Zimmer NexGen® Flex Knee system implanted in Plaintiff contained a manufacturing defect, in that it differed from the manufacturer's design or specifications, or from other typical units of the same product line.

157. Plaintiff's physicians employed the Zimmer NexGen® Flex Knee system in the manner in which the Zimmer NexGen® Flex Knee system was intended to be used, making such use reasonably foreseeable to Defendants.

158. The Zimmer NexGen® Flex Knee system as designed, manufactured, marketed and sold by Defendants reached Plaintiff without substantial change in its condition.

159. As alleged herein, Defendants knew and had reason to know that the Zimmer NexGen® Flex Knee system caused increased risks of harm to the Plaintiff and other consumers. Defendants consciously disregarded these increased risks of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Zimmer

NexGen® Flex Knee system; and continuing to market, promote, sell and defend the Zimmer NexGen® Flex Knee system.

160. Defendants' design, manufacture, marketing, promotion, defense and sale of the Zimmer NexGen® Flex Knee system was a substantial factor in causing Plaintiffs' injuries, as described herein.

161. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including the defective manufacture of the Zimmer NexGen® Flex Knee system, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; poor balance; difficulty walking; popping, clicking and grinding noises; bone erosion; loosening, impingement and/or detachment; and other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; lost wages; loss of earning capacity; and mental and emotional distress for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SECOND CAUSE OF ACTION
STRICT LIABILITY – DESIGN DEFECT

162. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

163. Prior to, on, and after the dates of Plaintiff's initial knee surgery, and at all relevant times, Defendants designed, distributed, manufactured, sold, and marketed the Zimmer NexGen® Flex Knee system for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States.

164. The Zimmer NexGen® Flex Knee system was "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the Zimmer NexGen® Flex Knee system was in a condition not suitable for its proper and intended use.

165. At all times herein mentioned, the Defendants designed, manufactured, distributed, marketed and sold the above-described Zimmer NexGen® Flex Knee system, which was implanted in Plaintiff, such that it was dangerous, unsafe, and defective in design.

166. The Zimmer NexGen® Flex Knee system implanted in Plaintiff was defective in design due including but not limited to its propensity to detach, disconnect, and/or loosen.

167. Plaintiff's physicians employed the Zimmer NexGen® Flex Knee system in the manner in which the Zimmer NexGen® Flex Knee system was intended to be used, making such use reasonably foreseeable to Defendants.

168. The Zimmer NexGen® Flex Knee system as designed, manufactured, marketed and sold by Defendants reached Plaintiff without substantial change in its condition.

169. As alleged herein, Defendants knew and had reason to know that the Zimmer NexGen® Flex Knee system caused increased risks of harm to the Plaintiff and other consumers. Defendants consciously disregarded these increased risks of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Zimmer NexGen® Flex Knee system; and continuing to market, promote, sell and defend the Zimmer NexGen® Flex Knee system.

170. Defendants' design, manufacture, marketing, promotion, defense and sale of the Zimmer NexGen® Flex Knee system was a substantial factor in causing Plaintiffs' injuries, as described herein.

171. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including the defective design of the Zimmer NexGen® Flex Knee system, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; poor balance; difficulty walking; popping, clicking and grinding noises; bone erosion; loosening, impingement and/or detachment; and other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; lost wages; loss of earning capacity; and mental and emotional distress for which he is entitled to

compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

THIRD CAUSE OF ACTION
STRICT LIABILITY – FAILURE TO WARN

172. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

173. Prior to, on, and after the dates of Plaintiff's initial knee surgery, and at all relevant times, Defendants manufactured, distributed, and sold the Zimmer NexGen® Flex Knee system for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States.

174. The Zimmer NexGen® Flex Knee system was "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the Zimmer NexGen® Flex Knee system was in a condition not suitable for its proper and intended use.

175. The Zimmer NexGen® Flex Knee system posed increased risks of harm and side effects that were known or knowable to Defendants by the use of scientific knowledge available before, at and after the time of manufacture, distribution, and sale of the Zimmer NexGen® Flex Knee system.

176. Defendants knew or should have known of the defective condition, characteristics, and risks associated with the Zimmer NexGen® Flex Knee system as described herein.

177. Defendants consciously disregarded the increased risks of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Zimmer NexGen® Flex Knee system; and continuing to market, promote, sell and defend the Zimmer NexGen® Flex Knee system.

178. The Zimmer NexGen® Flex Knee system that was manufactured, distributed, and sold by the Defendants to Plaintiff was in a defective condition that was unreasonably and substantially dangerous to any user or ordinary consumer of the device, such as Plaintiff.

179. Such ordinary consumers, including Plaintiff, would not and could not have

recognized or discovered the potential risks and side effects of the Zimmer NexGen® Flex Knee system as set forth herein.

180. The warnings and directions provided with the Zimmer NexGen® Flex Knee system by Defendants failed to adequately warn of the potential risks and side effects of the Zimmer NexGen® Flex Knee system and the dangerous propensities of the device, which risks were known or were reasonably scientifically knowable to Defendants.

181. Defendants' Zimmer NexGen® Flex Knee system components were expected to and did reach Plaintiff and his physicians without substantial change in their condition as manufactured, distributed, and sold by Defendants.

182. Plaintiff's physicians used the Zimmer NexGen® Flex Knee system in the manner in which the Zimmer NexGen® Flex Knee system was intended to be used, making such use reasonably foreseeable to Defendants.

183. Defendants' lack of sufficient instructions or warnings prior to, on, and after the dates of Plaintiff's initial knee surgery was a substantial factor in causing Plaintiff's injuries, losses and damages as set forth herein.

184. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' lack of sufficient instructions or warnings, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; poor balance; difficulty walking; popping, clicking and grinding noises; bone erosion; loosening, impingement and/or detachment; and other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; lost wages; loss of earning capacity; and mental and emotional distress for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

FOURTH CAUSE OF ACTION
NEGLIGENCE – DESIGN, MANUFACTURE & SALE

185. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint

as if fully set forth herein and further alleges as follows:

186. Prior to, on, and after the dates of Plaintiff's initial knee surgery, and at all relevant times, Defendants had a duty to exercise reasonable care in the design, testing, manufacture, marketing, sale, and/or distribution of the Zimmer NexGen® Flex Knee system for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States.

187. Prior to, on, and after the dates of Plaintiff's initial knee surgery, Defendants failed to exercise reasonable care and were negligent and careless in and about their design, testing, distribution, manufacture, advertising, sale and marketing of the Zimmer NexGen® Flex Knee system.

188. Prior to, on, and after the dates of Plaintiff's initial knee surgery, Defendants failed to perform adequate evaluation and testing of the Zimmer NexGen® Flex Knee system, where such adequate evaluation and testing would have revealed the propensity of the Zimmer NexGen® Flex Knee system to detach, disconnect, and/or loosen, and to cause pain, inhibition of the ability to walk, and to require revision surgery.

189. Prior to, on, and after the dates of Plaintiff's initial knee surgery, Defendants had received complaints from healthcare providers that the Zimmer NexGen® Flex Knee system caused serious complications including detachment, disconnection, and/or loosening, but Defendants nonetheless consciously decided not to: perform any further testing on the Zimmer NexGen® Flex Knee system; investigate the root cause of these complications; suspend sales and distribution; or warn physicians and patients of the propensity of the device to detach, disconnect, and/or loosen.

190. Defendants' negligence in design, testing, distribution, manufacture, advertising, sales, and marketing prior to, on, and after the dates of Plaintiff's initial knee surgery was a substantial factor in causing Plaintiffs' injuries, losses, and damages, as described herein.

191. As alleged above, Defendants knew and had reason to know that the Zimmer NexGen® Flex Knee system caused increased risk of harm to Plaintiff and other consumers. Defendants consciously disregarded this increased risk of harm by failing to warn of such risks;

unlawfully concealing the dangerous problems associated with implantation of the Zimmer NexGen® Flex Knee system; and continuing to market, promote, sell and defend the Zimmer NexGen® Flex Knee system.

192. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' failure to exercise reasonable care as described herein, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; poor balance; difficulty walking; popping, clicking and grinding noises; bone erosion; loosening, impingement and/or detachment; and other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; lost wages; loss of earning capacity; and mental and emotional distress for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

FIFTH CAUSE OF ACTION
NEGLIGENCE – FAILURE TO WARN

193. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

194. Prior to, on, and after the dates of Plaintiff's initial knee surgery, and at all relevant times, Defendants designed, distributed, manufactured, sold, and marketed the Zimmer NexGen® Flex Knee system for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States.

195. Prior to, on, and after the dates of Plaintiff's initial knee surgery, Defendants knew or should have known that the Zimmer NexGen® Flex Knee system was dangerous or was likely to be dangerous when used in a reasonably foreseeable manner. Such danger included the propensity of the device to detach, disconnect, and/or loosen, cause pain, inhibit walking, and require revision surgery.

196. Prior to, on, and after the dates of Plaintiff's initial knee surgery, Defendants knew or reasonably should have known that the users of the device, including Plaintiff, would not realize

the dangers presented by the device.

197. Prior to, on, and after the dates of Plaintiff's initial knee surgery, Defendants failed to adequately warn of the dangers presented by the device and/or failed to instruct on the safe use of the device. Such failures to warn and/or instruct included, but were not limited to: failing to advise of the known or knowable risks, dangers, and side effects associated with the use of the Zimmer NexGen® Flex Knee system; failing to properly advise of the means and methods available for the elimination of the risks, dangers, and side effects associated with the Zimmer NexGen® Flex Knee system, including detachment, disconnection, and/or loosening from the acetabulum; failing to warn physicians about the risks, dangers, and side effects associated with the Zimmer NexGen® Flex Knee system, including the rate of detachment, disconnection, and/or loosening, as well as associated complications; and failing to warn consumers about the risks, dangers, and side effects associated with the Zimmer NexGen® Flex Knee system, including the rate of detachment, disconnection, and/or loosening, as well as associated complications, and the signs and symptoms of detachment, disconnection, loosening and/or associated complications for which medical attention should be sought.

198. Reasonable manufacturers and reasonable distributors, under the same or similar circumstances as those of Defendants prior to, on, and after the dates of Plaintiff's initial knee surgery, would have warned of the dangers presented by the Zimmer NexGen® Flex Knee system, or instructed on the safe use of the Zimmer NexGen® Flex Knee system.

199. Prior to the dates of Plaintiff's initial knee surgery, the Zimmer NexGen® Flex Knee system had already caused numerous instances of the detachment, disconnection and/or loosening. Defendants consciously decided neither to warn physicians or patients of the Zimmer NexGen® Flex Knee system's increased propensity to cause these serious complications, nor of the signs and symptoms of these complications.

200. Defendants' negligent failure to warn Plaintiff or Plaintiff's healthcare providers prior to, on, and after the dates of Plaintiff's initial knee surgery was a substantial factor in causing Plaintiffs' injuries, losses and damages as described herein.

201. As alleged above, Defendants knew and had reason to know that the Zimmer NexGen® Flex Knee system caused increased risk of harm to the Plaintiffs and other consumers. Defendants consciously disregarded this increased risk of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Zimmer NexGen® Flex Knee system; and continuing to market, promote, sell and defend the Zimmer NexGen® Flex Knee system.

202. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' negligent failure to warn, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; poor balance; difficulty walking; popping, clicking and grinding noises; bone erosion; loosening, impingement and/or detachment; and other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; lost wages; loss of earning capacity; and mental and emotional distress for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SIXTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

203. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

204. Defendants impliedly warranted that the Zimmer NexGen® Flex Knee system, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiff, was merchantable and fit and safe for ordinary use.

205. Defendants further impliedly warranted that the Zimmer NexGen® Flex Knee system, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiff, was fit for the particular purposes for which it was intended and was sold.

206. Contrary to these implied warranties, the Zimmer NexGen® Flex Knee system was defective, unmerchantable, and unfit for its ordinary use when sold, and unfit for the particular

purpose for which it was sold.

207. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' breach of implied warranties, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; poor balance; difficulty walking; popping, clicking and grinding noises; bone erosion; loosening, impingement and/or detachment; and other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; lost wages; loss of earning capacity; and mental and emotional distress for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SEVENTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTIES

208. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

209. Defendants expressly warranted to Plaintiff by and through Defendants and/or their authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, patients, Plaintiff, and the general public, that the Zimmer NexGen® Flex Knee system was safe, effective, fit and proper for its intended use.

210. In allowing the implantation of the Zimmer NexGen® Flex Knee system, Plaintiff and Plaintiff's physicians relied on the skill, judgment, representations, and express warranties of Defendants.

211. These warranties and representations were false in that the Zimmer NexGen® Flex Knee system was not safe and was unfit for the uses for which it was intended.

212. Through the sale of the Zimmer NexGen® Flex Knee system, Defendants are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

213. Defendants breached their warranty of the mechanical soundness of the Zimmer NexGen® Flex Knee system by continuing sales and marketing campaigns highlighting the safety

and efficacy of their product, while they knew of the defects and risk of product failure and resulting patient injuries as described herein.

214. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' breach of express warranties, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; poor balance; difficulty walking; popping, clicking and grinding noises; bone erosion; loosening, impingement and/or detachment; and other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; lost wages; loss of earning capacity; and mental and emotional distress for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

EIGHTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

215. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

216. At the time Defendants manufactured, designed, marketed, sold and distributed the Zimmer NexGen® Flex Knee system for use by Plaintiff, Defendants knew or should have known of the use for which the Zimmer NexGen® Flex Knee system was intended and the serious risks and dangers associated with such use of the Zimmer NexGen® Flex Knee system.

217. Defendants owed a duty to treating physicians and to the ultimate end-users of the Zimmer NexGen® Flex Knee system, including Plaintiff, to accurately and truthfully represent the risks of Zimmer NexGen® Flex Knee system.

218. Defendants breached their duty by misrepresenting and/or failing to adequately warn Plaintiff's physicians, the medical community, Plaintiff, and the public about the risks of the Zimmer NexGen® Flex Knee system, which Defendants knew or in the exercise of diligence should have known.

219. Among Defendants' numerous misrepresentations and misleading omissions to

Plaintiff, Plaintiff's physicians and the general public are Defendants 'assurances to orthopedic surgeons that the Zimmer NexGen® Flex Knee system was safe, was the best product on the market, had an excellent track record and a low and acceptable failure rate. Defendants stated or implied to orthopedic surgeons that any problem with the Zimmer NexGen® Flex Knee system in a particular patient was attributable to "surgical technique." Defendants made such statements even after they became aware of numerous and serious complications with the Zimmer NexGen® Flex Knee system. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other "bad data" during their meetings with orthopedic surgeons.

220. Despite their knowledge of serious problems with the Zimmer NexGen® Flex Knee system, Defendants urged their sales representatives to continue marketing the Zimmer NexGen® Flex Knee system, and distributed medical literature and other communications to surgeons in an effort to mislead them and the general public about the adverse event rate and reasons for the Zimmer NexGen® Flex Knee system's failure.

221. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' negligent misrepresentations, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; poor balance; difficulty walking; popping, clicking and grinding noises; bone erosion; loosening, impingement and/or detachment; and other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; lost wages; loss of earning capacity; and mental and emotional distress for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

NINTH CAUSE OF ACTION
INTENTIONAL MISREPRESENTATION

222. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

223. Defendants, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote and sell the Zimmer NexGen® Flex Knee system, owed a duty to provide accurate and complete information to Plaintiff, his physicians, and the public regarding the Zimmer NexGen® Flex Knee system.

224. However, Defendants misled Plaintiff, Plaintiff's physicians, and the public into believing that the Zimmer NexGen® Flex Knee system was safe and effective for use in knee replacement surgery; engaged in deceptive, misleading and unconscionable promotional and sales methods to convince health care professionals and patients to use the Zimmer NexGen® Flex Knee system, even though Defendants knew or should have known that the Zimmer NexGen® Flex Knee system was unreasonably unsafe. Defendants also failed to warn health care professionals and the public about the safety risks of the Zimmer NexGen® Flex Knee system they designed, marketed and sold.

225. Defendants' advertising program and promotional items, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the Zimmer NexGen® Flex Knee system was safe for human use, had no unacceptable side effects, and would not interfere with daily life.

226. Defendants purposefully concealed, failed to disclose, misstated, downplayed and understated the health hazards and risks associated with the use of the Zimmer NexGen® Flex Knee system. Defendants, through promotional practices as well as the publication of medical literature, deceived potential treating physicians, Plaintiff, other patients, and the public. Defendants falsely and deceptively kept relevant information from potential treating physicians, the FDA and the general public, including Plaintiff, regarding the safety of the Zimmer NexGen® Flex Knee system.

227. Defendants expressly denied that the Zimmer NexGen® Flex Knee system created an increased risk of injury and took affirmative steps to prevent the discovery and dissemination of any evidence on the increased likelihood of injury from the Zimmer NexGen® Flex Knee system.

228. Defendants did not accurately report the results of adverse events by fraudulently and intentionally withholding from the FDA, physicians, Plaintiff, and the public, the truth regarding Zimmer NexGen® Flex Knee system failures for months, if not years, all the while undertaking a major advertising campaign to sell the Zimmer NexGen® Flex Knee system. Defendants received reports of the Zimmer NexGen® Flex Knee system defects from various sources, including those mentioned above, and intentionally withheld this information, while continuing to sell the Zimmer NexGen® Flex Knee system for implantation in individuals such as Plaintiff.

229. Further, even as Defendants disclosed some information regarding the Zimmer NexGen® Flex Knee system defects, the disclosures were incomplete and misleading.

230. Defendants effectively deceived and misled the scientific and medical communities regarding the risks and benefits of the Zimmer NexGen® Flex Knee system. Defendants failed to fully inform physicians, patients, including Plaintiff, and the public of the true defects in the Zimmer NexGen® Flex Knee system, defects that were known to Defendants, and continued to assure physicians and patients that the Zimmer NexGen® Flex Knee system was adequate and reliable for the purpose intended and continue to sell the Zimmer NexGen® Flex Knee system.

231. Through the materials they disseminated, Defendants falsely and deceptively misrepresented and omitted a number of material facts regarding the Zimmer NexGen® Flex Knee system.

232. Defendants possessed evidence demonstrating the Zimmer NexGen® Flex Knee system caused serious adverse side effects. Nevertheless, Defendants continued to market the Zimmer NexGen® Flex Knee system by providing false and misleading information with regard to its safety to Plaintiff and Plaintiff's treating physicians.

233. Among Defendants' numerous misrepresentations and misleading omissions to Plaintiff, Plaintiff's physicians and the general public are Defendants' assurances to orthopedic surgeons that the Zimmer NexGen® Flex Knee system was safe, was the best product on the market, had an excellent track record and a low and acceptable failure rate. Defendants stated or

implied to orthopedic surgeons that any problem with the Zimmer NexGen® Flex Knee system in a particular patient was attributable to "surgical technique." Defendants made such statements even after they became aware of numerous and serious complications with the Zimmer NexGen® Flex Knee system. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other "bad data" during their meetings with orthopedic surgeons.

234. Despite their knowledge of serious problems with the Zimmer NexGen® Flex Knee system, Defendants urged their sales representatives to continue marketing the Zimmer NexGen® Flex Knee system, and distributed medical literature and other communications to surgeons in an effort to mislead them and the general public about the adverse event rate and reasons for the Zimmer NexGen® Flex Knee system's failure.

235. Defendants engaged in all the acts and omissions described herein with the intent that Plaintiff's physicians and Plaintiff would rely on the misrepresentation, deception and concealment in deciding to use Defendants' Zimmer NexGen® Flex Knee system rather than another Zimmer product or a competitors' similar product.

236. Plaintiff and Plaintiff's physicians justifiably relied to their detriment on Defendants' intentional and fraudulent misrepresentations as described herein. This reliance proximately caused Plaintiff's injuries and damages as described herein.

237. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' deceptive, misleading and unconscionable promotional and sales methods, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; poor balance; difficulty walking; popping, clicking and grinding noises; bone erosion; loosening, impingement and/or detachment; and other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; lost wages; loss of earning capacity; and mental and emotional distress for which he is entitled to compensatory and equitable damages and declaratory relief in

an amount to be proven at trial.

TENTH CAUSE OF ACTION
CONSTRUCTIVE FRAUD

238. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

239. At the time Defendants sold the Zimmer NexGen® Flex Knee system to Plaintiff, Defendants were in a unique position of knowledge concerning the safety and effectiveness of the Zimmer NexGen® Flex Knee system, which knowledge was not possessed by Plaintiff or his physicians, and Defendants thereby held a position of superiority over Plaintiff and his physicians.

240. Through their unique knowledge and expertise regarding the defective nature of the Zimmer NexGen® Flex Knee system, and through their statements to physicians and their patients in advertisements, promotional materials, and other communications, Defendants professed to Plaintiff that they had knowledge of the truth of the representation that the Zimmer NexGen® Flex Knee system was safe and effective for its intended use and was not defective.

241. Defendants' representations to Plaintiff, the medical community, and the public were unqualified statements made to induce Plaintiff and Plaintiff's physicians to purchase and use the Zimmer NexGen® Flex Knee system; and Plaintiff and his physicians relied upon the statements when purchasing the devices and having them implanted in his body.

242. Defendants have made numerous misrepresentations and misleading omissions to Plaintiff, Plaintiff's physicians and the general public. Among these misrepresentations are Defendants 'assurances to orthopedic surgeons that the Zimmer NexGen® Flex Knee system was safe, was the best product on the market, had an excellent track record and a low and acceptable failure rate. Defendants stated or implied to orthopedic surgeons that any problem with the Zimmer NexGen® Flex Knee system in a particular patient was attributable to "surgical technique." Defendants made such statements even after they became aware of numerous and serious complications with the Zimmer NexGen® Flex Knee system. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other "bad

data" during their meetings with orthopedic surgeons.

243. Despite their knowledge of serious problems with the Zimmer NexGen® Flex Knee system, Defendants urged their sales representatives to continue marketing the Zimmer NexGen® Flex Knee system, and distributed medical literature and other communications to surgeons in an effort to mislead them and the general public about the adverse event rate and reasons for the Zimmer NexGen® Flex Knee system's failure.

244. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff and engaged in constructive fraud in their relationship with Plaintiff. Plaintiff reasonably relied on Defendants' representations to his detriment as described herein.

245. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants engaging in constructive fraud in their relationship with Plaintiff and his physicians, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, pain, suffering and discomfort; poor balance; difficulty walking; popping, clicking and grinding noises; bone erosion; loosening, impingement and/or detachment; and other physical injuries presently undiagnosed; economic damages; medical expenses; cost of past and future medical care including unnecessary and additional surgeries; rehabilitation; home health care; lost wages; loss of earning capacity; and mental and emotional distress for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

ELEVENTH CAUSE OF ACTION
VIOLATION OF MAINE'S UNFAIR TRADE PRACTICES ACT
(5 M.R.S.A. §§ 205-A – 214)

246. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

247. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and/or sale of the Zimmer NexGen® Flex Knee system.

248. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Zimmer NexGen® Flex Knee system and would not have incurred related medical costs.

249. Specifically, Plaintiff and his physicians were misled by the deceptive conduct as described herein.

250. Defendants' deceptive, unconscionable, and/or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of 5 M.R.S.A. §§ 205-A – 214.

251. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiff for the Zimmer NexGen® Flex Knee system that he would not have paid had Defendants not engaged in unfair and deceptive conduct.

252. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive, and/or fraudulent acts or trade practices in violation of 5 M.R.S.A. §§ 205-A – 214.

253. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create a demand for and sell the Zimmer NexGen® Flex Knee system. Each aspect of Defendants' conduct combined to artificially create sales of the Zimmer NexGen® Flex Knee system.

254. The medical community relied upon Defendants' misrepresentations and omissions in determining which antibiotic to utilize.

255. By reason of the unlawful acts engaged in by Defendants, Plaintiff has suffered ascertainable loss and damages.

256. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff was damaged by paying in whole or in part for the Zimmer NexGen® Flex Knee system. As a direct and proximate result of Defendants' violations 5 M.R.S.A. §§ 205-A – 214, Plaintiff has sustained

economic losses and other damages for which he is entitled to statutory and compensatory damages, and declaratory relief, in an amount to be proven at trial.

PUNITIVE DAMAGES

257. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

258. Plaintiff is entitled to punitive damages because the Defendants' breaches of their duties to Plaintiff were deliberate, intentional, and/or motivated by malice or ill will to Plaintiff.

259. Defendants intentionally misled Plaintiff, his health care providers, the medical community, and the public at large by making false representations about the safety of the Zimmer NexGen® Flex Knee system.

260. Defendants intentionally downplayed, understated and/or misrepresented their actual knowledge of the potential for serious injury with the use of Zimmer NexGen® Flex Knee system despite available information demonstrating that the Zimmer NexGen® Flex Knee system was likely to cause serious injuries to consumers.

261. Defendants were in possession of evidence demonstrating that the Zimmer NexGen® Flex Knee system caused serious injuries to consumers. Nevertheless, Defendants continued to market the Zimmer NexGen® Flex Knee system by providing false and misleading information to the Plaintiff and the general public with regard to the safety and efficacy of the device.

262. Defendants' outrageous actions as described herein were performed willfully, intentionally, and with malice in their disregard for the rights of the Plaintiff and the general public.

263. Accordingly, Plaintiff seeks and is entitled to punitive or exemplary damages in an amount to be determined at trial.

CONDITIONS PRECEDENT

264. All conditions precedent to Plaintiff's right to recover herein and to Defendants' liability have been performed or have occurred.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, as follows:

1. Compensatory damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all his injuries and damages, both past and present;
2. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of his injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent instability and loss of balance, and pain and suffering.
3. Double or triple damages as allowed by law;
4. Attorneys' fees, expenses, and costs of this action;
5. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and
6. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

Dated: January 22, 2015

Respectfully submitted,
LEWIS SAUL & ASSOCIATES, P.C.

/s/ Kevin M. Fitzgerald
Kevin M. Fitzgerald, Maine Bar No. 9373
183 Middle Street, Suite 200
Portland, ME 04101

Phone: (207) 874-7407
Fax: (207) 874-4930
Email: kfitzgerald@lewissaul.com

Attorneys for Plaintiff